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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,917	07/09/2001	Motohito Kanashima	2001-0971A	2734

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EXAMINER

GRUN, JAMES LESLIE

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/869,917

Applicant(s)  
KANASHIMA et al.

Examiner  
James L. Grun, Ph.D.

Art Unit  
1641



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The disclosure is objected to because of the following informalities: the specification is replete with grammatical, idiomatic, and spelling errors and should be carefully revised, for example, page 5, line 12, and page 7, lines 12 and 21, --antigenicity-- is misspelled. Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-4, the interrelationships of the steps and components of the method are not clear because it is not clear, inter alia, how an immunoassay of the preamble relates to the measuring step or to what reagents thrombin and/or antibody binding to fibrin-like related substances are added. The recitation of “fibrin-like related substances” is vague and indefinite because it is entirely unclear how like or related to fibrin a substance needs to be for antibodies binding thereto to be encompassed

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within the metes and bounds of the subject matter for which applicant desires coverage because there is no standard for ascertaining the requisite degree of likeness or relatedness.

In claim 2, it is not clear how the recited components are “used” as the thrombin. The examiner would suggest --wherein the thrombin is...--.

5            Claims 3 and 4 claim identical subject matter. In these claims it is not clear how the recited components are “used” as the antibody. The examiner would suggest --wherein the antibody is...--.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

10            (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15            (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

20            This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuda et al. (U.S. Pat. No. 4,780,410) in view of Lämmle et al. and Weir et al.

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Matsuda et al. teach a sandwich immunoassay for determination of Protein Induced by Vitamin K Absence or Antagonist-II/PIVKA-II/descarboxylated prothrombin in which an immobilized anti-PIVKA-II monoclonal antibody captures antigen from sample and labelled polyclonal anti-prothrombin antibodies detect captured antigen. In contrast to the invention as  
5 instantly claimed the reference does not teach addition of thrombin and/or antibodies specific for fibrin.

Lämmle et al. teach the structure of PIVKA-II and prothrombin.

Weir et al. teach that it is notoriously old and well known in the art that a multispecific antiserum can be made more specific by the absorption of undesired reactivities with soluble antigen.

10 It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have absorbed the polyclonal anti-prothrombin antibodies of Matsuda et al. with a soluble antigen, such as thrombin, having an undesirable cross-reactivity with the target antigen in view of the teachings of Weir that this is a notoriously old and well known method of increasing the specificity of a multispecific antiserum. Addition of soluble thrombin would have been expected  
15 to improve the specificity of the antibody preparation for detection of PIVKA-II in serum because one would have reasonably expected, in view of the well known structure of prothrombin and thrombin (Lämmle et al.), that variable levels of thrombin present in a sample of serum would unpredictably affect the proportion of antibodies in the polyclonal reagent available for binding to the target antigen, PIVKA-II, and one would have had ample motivation to reduce this expected  
20 undesirable cross-reaction.

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Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


5           Watanabe et al. (U.S. Pat. No. 5,516,640) teach determination of PIVKA other than PIVKA-II with a sandwich immunoassay comprising solid-phase immobilized anti-PIVKA-II monoclonal antibody. The reference teaches PIVKA-II as a good marker for hepatocellular carcinoma.


10           Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

          If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

15           The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

          Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.

20             
James L. Grun, Ph.D.  
September 24, 2003

  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800-1641